UNCLAS SECTION 01 OF 02 TAIPEI 000313

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STATE FOR EAP/RSP/TC AND EB/TPP/MTA/IPC, STATE PASS AIT/W
FOR RUZICKA AND USTR FOR KI AND FREEMAN, DOC FOR MBMORGAN

E.O. 12958: N/A
TAGS: ECON ETRD KIPR TW IPR
SUBJECT: TAIWAN PASSES DATA EXCLUSIVITY BILL

¶1. Summary: After striking a compromise the last week of the legislative session, Taiwan's Legislative Yuan (LY) passed a bill that will provide protection for pharmaceutical data in accordance with Taiwan's WTO commitments under TRIPS. The new law will protect test data for new drugs with new ingredients for five years. Pharmaceutical companies must apply to register their drugs in Taiwan within three years of release in an advanced country market. The research pharmaceutical industry in Taiwan is grudgingly pleased, but disappointed that a provision that would protect new indications and administrations was deleted from the compromise version. A local industry association has been awarded a grant to study the drug registration system in advance of a plan by the LY to consider amendments to the pharmaceutical law in the next session. Representatives from international manufacturers have not been invited to participate. End Summary.

¶2. Four separate bills to provide protection for pharmaceutical data were merged into one compromise bill on January 12, for consideration during the last week of the LY session. Despite a contentious battle over the national budget and threats from both sides to take procedural actions that would derail the passage of remaining bills, the DE bill was approved by a voice vote early the morning of January 21, the last day of the legislative session.

¶3. The compromise bill provides five years of protection for new pharmaceutical products with new ingredients. However, a provision that would have extended protection for other new drugs (i.e., new indications and administrations of previously approved drugs) for an additional three years was deleted. New pharmaceutical products with new ingredients are required to apply for registration with the Taiwan health authorities within three years of approval for use in one of ten advanced foreign countries (including the US, EU, and Japan, but excluding India and Russia) or face loss of protection.

¶4. Representatives from the International Research Pharmaceutical Manufacturers Association (IRPMA) were pleased that the bill had passed and were resigned to the idea that this bill was the best that could be expected now. While disappointed that protection for "other new drugs" was deleted, their disappointment was tempered by a clarification in the law specifying that new pharmaceutical products must only begin the Taiwan application process within three years of approval in an advanced country market to avail of DE protection, rather than requiring the registration process be completed within three years. Given their sometimes difficult relationship with the Department of Health, Bureau of Pharmaceutical Affairs, IRPMA has vowed to closely follow the drafting of implementing regulations to ensure that these are consistent with their understanding of the provisions of the bill.

¶5. IRPMA also expressed concern that plans by the LY to codify provisions of the drug registration system have thus far not taken into account the views of international research pharmaceutical companies. The Taiwan Pharmaceutical Manufacturers Association (TPMA) has been awarded a grant by the LY to complete a study of the registration system in preparation for proposed amendments to the pharmaceutical law but IRPMA member companies have not been consulted.

¶6. Comment: The passage of the DE bill fulfills a promise made by recently resigned Vice Minister of Health Chang Hong-jen to Assistant USTR Charles Freeman during the latter's July 2004 visit to Taiwan, later repeated by DOH Minister Chen to the AIT Deputy Director in August 2004 and by Deputy Minister of Economic Affairs Steve Chen during the November 2004 Trade and Investment Framework Agreement (TIFA) meeting. Passage comes despite reported efforts from within the Department of Health to undermine the bill in an attempt to protect local industry. While a few Taiwan research based pharmaceutical companies will also benefit from the new protections, most observers believe the passage of this new law is a direct response to U.S. preconditions for improving the U.S./Taiwan trade relationship in preparation for a Free Trade Agreement and removal from the Special 301 Watch List. Despite any shortcomings in the new law, Taiwan officials are likely to point to its passage as one more reason the U.S. should consider negotiating an FTA with Taiwan. End Comment.

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